UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

UNITED STATES OF AMERICA, Ex rel. Jeffrey Webb,	)	
Plaintiff	)	
v.	)	1:13-cv-00169-DBH
MILLER FAMILY ENTERPRISE, et al.,	)	
Defendants	)	

RECOMMENDED DECISION ON MOTION TO DISMISS AND MOTION FOR LEAVE TO AMEND

Plaintiff/Relator Jeffrey Webb (Relator) commenced this action against Defendants Miller Family Enterprise and M Drug, LLC under the *qui tam* provisions of the federal False Claims Act. The matter is before the Court on Defendants' Motion to Dismiss the Relator's Amended Complaint (ECF No. 37), and Plaintiff's Motion for Leave to File Amended Complaint to Revise Paragraph 30 (ECF No. 43). Upon review of the pleadings, and after consideration of the parties' arguments, the recommendation[1] is that the Court deny Relator's motion to amend and grant Defendants' motion to dismiss.

PROCEDURAL BACKGROUND

Relator filed the complaint in this matter on May 7, 2013. On July 1, 2013, the United States declined to exercise its right to intervene, and Relator subsequently served the complaint on Defendants. In response to the complaint, Defendants filed a motion to dismiss. Without

[1] The Court referred the motions for report and recommended decision.

objection, the Court granted Relator's request to amend the complaint. As a result, the Court declared Defendants' first motion to dismiss to be moot.

Relator filed the amended complaint on December 23, 2013 (ECF No. 35). In response to the amended complaint, Defendants filed the pending motion to dismiss (ECF No. 37). In his opposition to the motion (ECF No. 42), Relator requested leave to amend a paragraph of the amended complaint, which request the Clerk docketed as Relator's Motion for Leave to File Amended Complaint to Revise Paragraph 30 (ECF No. 43). On May 14, 2014, the parties presented oral argument on the pending motions.

FACTUAL BACKGROUND

The facts set forth herein are derived from Relator's Complaint, which facts are deemed true when evaluating the motion to dismiss.[2] *Beddall v. State St. Bank & Trust Co.*, 137 F.3d 12, 16 (1st Cir. 1998). In addition, the Court can also consider documents the authenticity of which are not disputed by the parties, public records, documents central to Relator's claim, and documents sufficiently referred to in the complaint. *Alternative Energy, Inc. v. St. Paul Fire and Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001).

On behalf of the United States, Relator seeks to recover funds allegedly obtained by Defendants in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. According to Relator's amended complaint, Defendants sold pharmaceutical drugs to various care facilities and received payment through certain United States government programs. Some of the purchasers of the drugs occasionally returned unused and sealed drugs in their original containers. Defendants lawfully dispensed the returned drugs to others, without providing a refund or credit to the government

[2] The reference to the facts as alleged should not be construed as a determination that the alleged facts are accurate. The alleged facts are recited in the context of the standard of review for a motion to dismiss.

program for its initial purchase. Relator also alleges that Defendants failed to maintain required documents related to returned and re-dispensed drugs.

Relator worked for Defendants from September 2004 to April 2012, including as Defendants' long term care operations manager. (Am. Compl. ¶ 7, ECF No 35.) Defendants are related Maine corporations with a principal place of business in Bangor, Maine. At the time of the alleged conduct, Defendants did business as Miller Drug and Miller Drug LTC. (*Id.* ¶ 8.) In this capacity, Defendants operated as pharmacies and provided prescription drugs to patients residing at various care facilities. (*Id.* ¶ 11.)[3]

Defendants regularly filled prescription drug orders issued by area care facilities, including Bangor Nursing and Rehab, Birchwood Living Center, Collier's Nursing Home, Colonial Healthcare, Cummings Healthcare, Eastside Rehab, Eastside Rehab and Living Center, Katahdin Nursing Home, Maine Veterans' Home in Bangor, Opportunity Housing (a/k/a OHI), Orono Commons, Penobscot Job Corps, Penobscot Nursing Home, Siesta Haven, Stillwater Healthcare, Wellspring Men, Wellspring Women, Westgate Manor, Woodlands of Brewer, and Winterberry Heights. (*Id.* ¶¶ 11, 18, 28.)

When Defendants filled the prescriptions, they billed the facilities, which billed Medicare, MaineCare (Medicaid), Tri-Care, and FEHB programs for the cost of those drugs. (*Id.* ¶ 11.) Regularly, facilities returned to Defendants sealed, unused portions of patients' medications. (*Id.*) Defendants accepted the returns and later (lawfully) resold the drugs. (*Id.*) Relator asserts that Defendants routinely did not issue a refund or credit to the federally-funded payors in connection with the returns. As a consequence, Medicare, MaineCare, Tri-Care, and the FEHB programs did

[3] In June 2010, Defendants merged with another corporation, Affiliated. (*Id.*) As of the merger, the refund-related practices about which Relator complains ended. (*Id.*)

not receive reimbursement for the returned drugs. (*Id.*) Relator contends that Defendants "would later resell" the returned drugs. (*Id.*)

MAR forms

On a monthly basis, Defendants provided the facilities that they serviced with Medication Administration Record (MAR) forms. The facilities would return the completed MAR forms with new orders, new patients to whom the medications would be administered, and changes in directions and hours of administration. Before and after the Affiliated merger, Defendants entered only a portion of that information into Defendants' computers. The forms were subsequently destroyed. (*Id.* ¶ 12.)

MaineCare return forms

In some instances, Defendants submitted claims for payment directly to MaineCare (Medicaid) for drugs provided to some of the patients at the facilities. Not infrequently, the facilities returned some of the drugs, for which MaineCare requires a return form in triplicate (one for the pharmacy, one for the facility, and one for the State). Relator alleges that Defendants often received from facilities all three copies of the form, returned to the facilities their copy, and retained or destroyed the state copy. According to Relator, the withholding of the state copy prevented "triggering a refund to be paid to MaineCare." (*Id.* ¶ 13.)

Certain uninvolved program payments

For the facilities-based claims, the only patients for whom the provision of drugs did not result in an increase in reimbursement from various federally-funded insurers were those skilled nursing patients eligible for limited Medicare Part A or B services. The prescription drug costs for those individuals were covered by a flat *per diem* fee. (*Id.* ¶¶ 16, 25.) Citing information that he derived from his work for Defendants, including as a purchaser, senior pharmacy coordinator,

and technician, Relator believes that the Medicare Part A or B reimbursement method applied to ten percent or fewer of all prescription drug claims.[4] All of the other drugs provided to facilities (the remaining 90 percent) were billed primarily to federal payors on a pass-through basis. (*Id.* ¶¶ 16-17.)

Medicare Part D and MaineCare billings/credits

Typically, if a patient was a Medicare Part D or MaineCare recipient, Defendants sent a bill directly to the Medicare Part D insurer or to MaineCare. According to Relator, for any refund for the prescription drugs returned for that patient, Defendants should have given a credit on the next monthly bill. Relator alleges that prior to June 2010, such credits were rarely given. (*Id.* ¶ 25.)

Relator's knowledge of Defendants' practices

Relator asserts that he was intimately aware of Defendants' billing and return practices. He worked with Kirk Bridges, an assistant store manager, in reviewing the bills and submitting them to the facilities for payment. (*Id.* ¶¶ 14, 22.) Relator also supervised Richard Russell, another employee, in processing sealed returns for Defendants. (*Id.* ¶ 15.) Relator had unfettered access to the prescription volume history and revenues for Defendants. He allegedly became aware that for patients at the care facilities, the primary payors for prescription drugs were Medicare Part D (the federal prescription drug program), MaineCare, and, to the extent that the patients were either retired military or retired federal employees, Tri-Care and the FEHB program, respectively. Each of the payors paid on a per-prescription basis. (*Id.* ¶ 16.)

[4] Relator alleges that monthly refund rates for a single nursing facility in 2010 and 2011 ranged between approximately $2700 and $5,000. (Am. Compl. ¶ 25.)

Alleged statements by other employees

After June 2010, Relator received phone calls from various employees of certain care facilities, in which communications the employees raised the question as to why refunds were now being issued to the facility. Relator responded that he would "look into it." (*Id.* ¶ 18.) Relator inquired of Ron Chase, the Pharmacist-in-Charge for Miller Drug, LTC, who responded: "I know Bill took back medications all the time without ever giving credit." The reference to "Bill" in this statement was to one of Defendants' principals, Bernard "Bill" Miller. Mr. Chase also stated that before the Affiliated merger, he had occasionally visited facilities and fielded inquiries as to whether there would be refunds for returned drugs. His standard response was "you'll have to check with Bill or Gloria." The reference to "Gloria" was a reference to Bill Miller's wife, Gloria Miller, who was also the bookkeeper. (*Id.* ¶ 19.) Kirk Bridges reported fielding similar inquiries and giving the same response. (*Id.* ¶ 22.) Mr. Bridges also confirmed Mr. Chase's assessment that Mr. Miller had always taken back medications without issuing refunds prior to the Affiliated merger. (*Id.*) On at least three occasions, Relator heard Mr. Miller state, in connection with this practice, "I'll be dead before they catch me." (*Id.* ¶ 20.)

Richard "Dickie" Russell, a processor for Defendants, told Relator: "Billy tells me to keep the records of who I get medications back from, the Facility, and how much the credit would be. He also says he'll stop by to get the credits from me for the meds so he could pay back the Facility. But . . . he never does. I haven't had him come up once to my office to look at those books for years." (*Id.* ¶ 24.) Mr. Russell maintained notes documenting the facilities that returned drugs, the cost of the drugs, and how Defendants handled the returned drugs. Relator, who has seen the notes, contends that refunds were not issued for the drugs returned. (*Id.* ¶ 26.)

With respect to drug returns associated with MaineCare payments, Defendants would ordinarily receive from the facilities that returned drugs all three sheets of the triplicate form required by MaineCare. In Relator's presence, Mr. Russell stated that Mr. Miller instructed him to withhold from the State of Maine the copy designated as the State's copy. (*Id.* ¶ 27.)

Facility records

Relator believes that each facility should have records of the medications that it returned because State Pharmacy Board regulations require close monitoring of prescription drugs that have been delivered to and returned by a facility. Relator also believes that similar documentation is required by state regulations governing the licensing and functioning of nursing facilities. (*Id.* ¶ 27.)

Based on this information, Relator believes that the following facilities returned drugs to Defendants prior to June 2010 and that the federally-funded insurer who paid for those drugs never received "refunds," directly or indirectly: Bangor Nursing and Rehab, Birchwood Living Center, Collier's Nursing Home, Colonial Healthcare, Katahdin Nursing Home, Maine Veterans' Home in Bangor, Opportunity Housing (a/k/a OHI), Orono Commons, Penobscot Job Corps, Penobscot Nursing Home, Siesta Haven, Stillwater Healthcare, Wellspring Men, Wellspring Women, and Winterberry Heights. (*Id.* ¶ 28.)

Concluding allegations

In his amended complaint, Relator asserts that Defendants have knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the Government. (*Id.* ¶ 30.) Because Defendants' motion to dismiss takes issue with Relator's wording in paragraph 30 of the

amended complaint, Relator requests in opposition that he be given leave to amend paragraph 30 to read as follows:

> 30. By virtue of the acts described above, Defendants have knowingly presented or caused to be presented to the United States a false or fraudulent claim for payment for [sic] approval in violation of former Section 3729(a)(1) and current Section 3729(a)(1)(A). Defendants have further knowingly had possession or control of money to be used by the government and knowingly caused to be delivered less than all of that money back to the government in violation of former Section 3729(a)(4) and current Section 3729(a)(1)(D). Defendants have further knowingly caused to be made a false record to conceal or decrease an obligation to pay or transmit money or property to the government in violation of former Section 3729(a)(7), and current Section 3729(a)(1)(G). Defendants have further knowingly concealed or improperly avoided an obligation to pay or transmit money to the government in violation of Section 3729(a)(1)(G).

(Relator's Opposition at 11, ECF No. 42.) Relator asks that the Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States sustained because of Defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729, plus other relief.

DISCUSSION

Through their motion, Defendants seek the dismissal of all claims. (Motion to Dismiss, ECF No. 37.) Defendants also oppose Relator's request for leave to amend further the complaint.

A. Standard of Review

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a party may seek dismissal if that party believes that the complaint fails "to state a claim upon which relief can be granted." In its assessment of the motion, the Court must "assume the truth of all well-plead facts and give the plaintiff[] the benefit of all reasonable inferences therefrom." *Blanco v. Bath Iron Works Corp.*, 802 F. Supp. 2d 215, 221 (D. Me. 2011) (quoting *Genzyme Corp. v. Fed. Ins. Co.*, 622 F.3d 62, 68 (1st Cir. 2010)). To overcome Defendants' motion, Relator's amended complaint must set forth factual allegations, either direct or inferential, for every material element needed to support

recovery under an identified legal theory. *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011).

Generally, a plaintiff may attempt to overcome a motion to dismiss by requesting leave to amend his complaint. Ordinarily, leave to amend should be granted freely, when justice so requires. Fed. R. Civ. P. 15(a)(2). However, it is appropriate for a court to deny leave to amend when the proposed amendments are futile because they fail to meet the pleading requirements of the Federal Rules. *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007); *see also Giuliano v. Nations Title, Inc.*, 134 F.3d 361 (1st Cir. 1998) (affirming order denying motion to amend and granting motion to dismiss where the plaintiff's allegations failed to satisfy the particularity pleading requirements of Rule 9(b)).

B. The False Claims Act

The False Claims Act (FCA) imposes liability on any person who, *inter alia*, "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," *id.* 3729(a)(1)(B). In addition, the FCA prohibits "reverse" false claims, in which a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* § 3729(a)(1)(G). Lastly in connection with this case, the FCA imposes liability on anyone who "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property." *Id.* § 3729(a)(1)(D). In enacting the FCA, "Congress wrote expansively,

meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cnty., Illinois v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert–White Co.*, 390 U.S. 228, 232 (1968)).

Consistent with the plain language of the statute, "liability cannot arise under the FCA unless a defendant acted knowingly." *U.S. ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 95 (1st Cir. 2012) (citing 31 U.S.C. § 3729(a)). The FCA defines "knowing" and "knowingly" to "mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). A defendant who knowingly seeks payment from the Government for amounts the Government does not owe is subject to liability, including pursuant to a *qui tam* claim pressed by a whistleblower (called a relator), who may retain a portion of the proceeds recovered for the Government. *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009). Although *qui tam* claims are subject to certain jurisdictional requirements designed to prevent "parasitic" actions, *id.*, Defendants have not raised any such jurisdictional challenge in the motion to dismiss.

In addition to the requirement of "knowing" conduct, where falsity or fraud is at issue, a defendant's claim or other statement "must contain a material defect." *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 388 (1st Cir. 2011). That defect does not need to be, in every instance, an express false statement of fact. Implied falsehoods suggesting that the claim is legitimate can suffice. *Id.* at 390-91. In addition, under some circumstances, recovery is possible without the need to identify a specific statute, regulation, or certification requirement that a party who sought payment from the Government violated. *Id.* at 391.

C. Analysis

1. Failure to issue a refund as a reverse false claim

A party is subject to liability on a reverse false claim theory if it "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). Alternatively, liability can arise for delivering to the Government less than what it is entitled to, *id.* § 3729(a)(1)(D), or for making or using a false record or statement material to an obligation to pay or transmit money or property to the Government, *id.* § 3729(a)(1)(G). As alleged by Relator, the existence of an obligation to pay or transmit money to the Government is an essential element of his reverse false claim.

Defendants argue that they were under no obligation to reimburse the Government for payments that the Government made for drugs that were returned to, and resold by, Defendants. Defendants thus contend that there can be no knowing violation of the FCA. (*Id.* at 15.) They maintain, contrary to Relator's allegations and argument, that Maine Department of Health and Human Services' regulations related to pharmaceutical services only apply to nursing facilities (10-144 C.M.R. ch. 17, § 17.D.8(c)), that the Maine Pharmacy Act permits re-dispensing drugs returned to stock in an unbroken, sealed container (32 M.R.S. § 13791), and that the mere existence of a triplicate MaineCare form related to drug returns does not impose on drug-dispensing pharmacies an obligation to reimburse the Government. (Motion to Dismiss at 7-12.)

Relator contends that when Defendants' Medicare Part D facility-customers returned prescription drugs that Defendants could re-dispense, Defendants should have provided the customers with refunds or credits. Relator, however, does not cite any authority (statutory,

regulatory, or contractual) by which such an affirmative obligation is imposed on Defendants as part of the Medicare Part D program. While the return of the drugs might provide the facilities with a basis to request a refund, the mere fact that the facilities could make such a request does not establish that Defendant was under an obligation to provide a refund in the absence of any such request. *Cf. U.S. ex rel. Booker v. Pfizer, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1271766, at *9 (D. Mass. Mar. 26, 2014) (observing that when an obligation to pay depends of "intervening discretionary governmental acts" there is no obligation to avoid if the discretionary act is not taken).

Relator asserts a parallel claim with respect to MaineCare (Medicaid). In support of this argument, Relator refers to language within the MaineCare Benefits Manual, section 1.03-3(B), "Requirements of Provider Participation," which requires, *inter alia*, that a provider "[n]otify the Department whenever there is a change in any of the information that the provider previously submitted to the Department." (Opposition at 4.) Not insignificantly, this provision does not impose a refund obligation. The changes in information contemplated by the provision are "a change in address, or the addition or deletion of staff from the practice." Although the Manual's directives regarding billing practices, including section 1.03-3(J) which states that a provider must "[b]ill only for covered services and supplies delivered," might provide some authority for Relator's direct false claim, the Manual is silent on the issue of a refund. The Manual, therefore, does not support Relator's argument that Defendants were obligated to issue a refund.

Relator also relies on his allegations regarding the triplicate MaineCare forms in an effort to establish an obligation upon Defendants to refund the funds paid for drugs that are resold. The parties dispute whether the various regulations impose upon Defendants a duty to submit the form to the state, which would purportedly "trigger" a refund. Regardless of whether Defendants were

obligated to submit a copy of the form to the state, Relator has cited no regulation that requires Defendants to refund any payments or issue a credit.[5] Relator's contention that submission of the form would "trigger" a demand for a refund is unsupported by any alleged fact or legal authority.[6]

In short, Relator fails to identify a statutory, regulatory, or contractual provision that imposed on Defendants an obligation to issue refunds when nursing care facilities returned drugs that could be re-dispensed, or that imposed on Defendants an obligation to set aside returned, re-dispensable drugs for future use within a government program. Relator thus has failed to state a reverse false claim.

2. Successive billing without adjustment as a direct false claim

In his opposition to Defendants' motion to dismiss, Relator maintains that the facts establish the basis for a direct false claim. In support of this argument, Relator cites 42 U.S.C. § 1396b, which governs payments made to the states through the Medicaid program. Relator requests leave to amend his complaint to introduce a specific direct false claim allegation to paragraph 30. (Opposition at 11, ECF No. 42/43.) As explained below, although under certain circumstances a direct false claim is actionable against a pharmacy, even with the requested amendment, Relator has not alleged facts with sufficient particularity to sustain a direct false claim.

[5] Relator cites Chapter 17 of the State of Maine's Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities. (Am. Compl. Ex. F, ECF No. 20-2, PageID # 114.) Chapter 17 is addressed to pharmaceutical services and includes a provision reading, "Individual unit doses, other than Schedule II through V controlled substances must be returned to the pharmacist and any credit or rebate made to person(s) who originally paid for the medication." (*Id.* ¶ 17.D.8.c.)

[6] Relator's reliance on the fact that the Maine Department of Professional and Financial Regulation, Maine Board of Pharmacy, imposes on pharmacists the legal obligation to conform to, *inter alia*, the Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities is misplaced. While the regulation references "any credit or rebate made," the regulation does not impose an obligation to issue a credit or grant a rebate. Instead, in context, the regulation simply provides that if a credit or rebate is given for any reason (e.g., as required by contract), the rebate must be paid to the original payor.

a. A direct false claim theory is actionable

Under the Medicaid Act,[7] Congress authorized states to establish plans for medical assistance, which plans would be supported by federal grant money. 42 U.S.C. § 1396a. As part of this statutory scheme, Congress directed that payments "shall not be made" to the states for certain items or services, including payment:

> with respect to any amount expended for reimbursement to a pharmacy under this subchapter for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment under this subchapter (other than with respect to a reasonable restocking fee for such drug).

Id. § 1396b(i)(10)(D). Through this provision, Congress has established that Medicaid funds cannot be used to pay on more than one occasion for the same prescription drug.

Relying on this provision, Relator argues that Defendants' alleged resale of drugs and re-billing of nursing care facilities for returned drugs constitutes a "direct false claim rather than a reverse false claim, as Defendants could not legally receive payment for a drug they were now selling to the government a second time." (Relator's Opposition at 3, ECF No. 42.) In response, Defendants assert that the Medicaid Act "directs the conduct of the government, not providers," and that the Act does not, in any event, impose a refund obligation. (Defendants' Reply at 3-5, ECF No. 44.) Contrary to Defendants' argument, whether Defendants were obligated to refund any payments is not part of the direct claim analysis. The issue is whether under the Medicaid regulations, Defendants' resale of returned drugs constitutes a direct false claim.

[7] "Medicaid provides federal funding to states that have established a qualifying plan to assist certain types of needy individuals in obtaining medical care and insurance, including Medicare." *Bourgoin v. Sebelius*, 296 F.R.D. 15, 18 (D. Me. 2013). In comparison, "Medicare is a health insurance program for those who are over age 65 or have certain disabilities." *Id.* (quoting *Massachusetts v. Sebelius*, 638 F.3d 24, 26 (1st Cir. 2011), and citing 42 U.S.C. §§ 1395 to 1395kkk–1 (2012)).

Medicaid will provide reimbursement for "covered outpatient drugs" only. *United States v. King-Vassel*, 728 F.3d 707, 715 (7th Cir. 2013) (citing, *inter alia*, 42 U.S.C. § 1396b(i)(10)); *U.S. ex rel. Worsfold v. Pfizer Inc.*, No. 1:2009-cv-11522, 2013 WL 6195790, at *3 (D. Mass. Nov. 22, 2013) (same). In other contexts, courts have determined a claim for a payment that "shall not be made" under the Medicaid Act is a false claim under the FCA. 42 U.S.C. § 1396b(i). For example, courts have concluded that the presentation of a claim for payment for services that violated the Medicaid Act's restrictions on physician referrals (42 U.S.C. § 1396b(s)) could be a false claim. *See United States v. All Children's Health Sys., Inc.*, No. 8:2011-cv-01687-T-27, 2013 WL 6054803, at *5-6 (M.D. Fla. Nov. 15, 2013); *United States v. Halifax Hosp. Med. Ctr.*, No. 6:2009-CV-1002-ORL-31, 2012 WL 921147, at *4 (M.D. Fla. Mar. 19, 2012). Courts also have allowed FCA claims to proceed where payment was requested for prescription drugs that are excluded from coverage under the Medicaid Act, including for prescribed medication "for a medical indication which is not a medically accepted indication," 42 U.S.C. §§ 1396b(i)(10)(A) (cross-referencing 42 U.S.C. § 1396r-8(a)(3)). *See King-Vassel*, 728 F.3d at 711; *United States v. Vassel*, No. 2:2011-cv-000236, 2013 WL 5946362, at *3 (E.D. Wis. Nov. 5, 2013) (addressing related discovery disputes). The submission of claims for reimbursement prohibited by Medicaid (i.e., a reimbursement that "shall not be made" under the Medicaid Act), therefore, can generate FCA liability.[8]

[8] Medicaid reimbursement works as follows:

> Medicaid provides "medical assistance on behalf of families with dependent children and of ... individuals[ ] whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396–1. Although the federal government ultimately foots much of the bill, the administration of the program is left to the states. In the case of prescription drugs, pharmacies pay pharmaceutical companies for drugs and then submit claims to the state Medicaid agency for reimbursement. 42 U.S.C. §§ 1396a(a)(23), (32). The federal government then reimburses the state. 42 U.S.C. § 1396–1. In that way, claims submitted to state Medicaid agencies are considered claims presented to the federal government and may serve as the basis for FCA liability. *See United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856 (7th Cir.2006) (discussing the necessity of an actual claim to Medicaid as a basis for FCA liability).

In this case, the Medicaid provision upon which Relator relies (42 U.S.C. § 1396b(i)(10)) is not materially different from the provisions that courts have concluded give rise to potential FCA liability. In essence, the Act expressly provides that the government will not pay a pharmacy on more than one occasion for a covered outpatient drug. According to Relator, a portion of the challenged payments was paid through the Medicaid program. Consequently, with Relator's newly proposed amendment, at least part of Relator's complaint would be premised on Defendants' presentation of successive claims for pharmacy reimbursement that were not covered by the Medicaid Act pursuant to 42 U.S.C. § 1396b(i)(10)(D).[9]

With 42 U.S.C. § 1396b(i)(10)(D), Relator has identified a statutory provision that would support a direct false claim theory of liability, particularly given Relator's additional reference to the MaineCare Benefits Manual, section 1.03-3(J), which states that a provider must "[b]ill only for covered services and supplies delivered."[10] The question remains whether Relator has alleged the fraud with sufficient particularity to sustain a claim under the FCA.

King-Vassel, 728 F.3d at 711.

[9] Defendants maintain that the structure of the Medicare Part D program, which informs another portion of Relator's action, rules out any inference that a duty exists for pharmacies to refund or credit money to the account of a plan or the Government generally. (Defendants' Reply at 5 n.4.) They note that plan sponsors are required to supply pharmacies with "terms and conditions . . . that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law." 42 C.F.R. § 423.154(f). Based on this, Defendants maintain that the availability of "credits for returned medications" is merely a matter of contract between the sponsors and pharmacies. (*Id.*) However, Defendants have not provided reliable authority for the proposition that a false claim cannot be premised on a knowing violation of a contract provision simply because the contract is with a plan sponsor rather than a governmental agency. Moreover, the mere presence of a private party intermediary does not insulate Defendants from potential FCA liability. Under the FCA, a "claim" includes "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that . . . is made to a *contractor*, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf . . . and if the United States Government . . . will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C.A. § 3729(b)(2)(A)(ii) (emphasis added). *See also Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 670 (2008).

[10] In *U.S. ex rel. Quinn v. Omnicare*, the Third Circuit Court of Appeals affirmed the entry of summary judgment for the defendant pharmacy in a similar action due to the relator's "failure to present evidence of the actual submission of a single false claim." 382 F.3d 432, 434 (3d Cir. 2004). At that time, Congress had not yet enacted the provision now codified at 42 U.S.C. § 1396b(i)(10)(D), which now expressly prohibits successive payment for the same drug.

b. The particularity of Relator's pleading

Defendants argue that Relator's allegation that Defendants "would later resell" previously-returned medication to unspecified buyers does not specifically allege successive billings of the Government for the same drug. (Defendants' Reply re Motion to Dismiss at 2, ECF No. 44, quoting Am. Compl. ¶ 11, ECF No. 35.) Additionally, assuming that Relator's allegations suggest a plausible inference that Defendants presented successive billings for the same drug in some unspecified instances, Defendants argue that to state successfully a false successive billing claim, Relator must allege the relevant facts and circumstances with specificity. (*Id.* at 6.)

Relator's direct false claim theory is subject to the heightened pleading requirements of Rule 9(b). *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009); *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 227-28 (1st Cir. 2004). To obtain leave to amend the complaint to assert a direct false claim theory, therefore, Relator must first present the Court with a pleading that sets forth the "circumstances constituting fraud" with "particularity." Fed. R. Civ. P. 9(b). Relator's complaint thus "must specify the time, place, and content of an alleged false representation." *Gagne*, 565 F.3d at 45. Unless Relator can do so, the Court should deny leave to amend on the basis of the proposed amendment's futility. *Rost*, 507 F.3d at 733.

Similarly, in *U.S. ex. Rel. Crews v. NCS Healthcare of Ill., Inc.*, the Seventh Circuit affirmed the entry of summary judgment for the defendant pharmacy where the relator failed to prove that a "given pharmaceutical" was paid for by Medicaid, returned, and rebilled to Medicaid. 460 F.3d 853, 856 (7th Cir. 2006) (quoting *Quinn*, 382 F.3d at 440). There is no mention of section 1396b(i)(10)(D) in the opinion, likely because it was not enacted when the claims at issue were presented). *See* Deficit Reduction Act of 2005, Pub. L. No. 109–171, § 6033, 120 Stat 4 (2006) ("Prohibition on Restocking and Double Billing of Prescription Drugs"). These cases reflect that at least two circuit courts of appeals were willing to assume, at least for the sake of argument, that successive billings could give rise to false claims liability, even in the absence of federal legislation supporting that conclusion.

To allege a false claim with particularity, Relator must "specify the who, what, where, and when of the allegedly false or fraudulent representation." *Gagne,* 565 F.3d at 45 (quoting *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)). This requires that the complaint include "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, [and] the amount of money charged to the government." *Karvelas,* 360 F.3d at 233. "[S]ome of this information for at least some of the claims *must* be pleaded in order to satisfy Rule 9(b)." *Id.* (emphasis added). Indeed, evidence of an actual false claim is "the *sine qua non* of a False Claims Act violation." *Id.* at 225. "[I]t is the fraud itself which must be pled with particularity, not just who benefits from the fraud and what pot of federal money may be the object of the fraud." *Gagne,* 565 F.3d at 47.

Relator contends he has satisfied the particularity requirement through his identification of the who (Defendants), the what (double billing of the federal program payors in question) and "inferentially the times, amounts and circumstances of payments." (Relator's Opposition to Defendants' Motion to Dismiss at 9, ECF No. 42.) More specifically, Relator relies upon certain refunds provided under new management, albeit refunds to different payors who comprise,[11] allegedly, only ten percent of Defendants' total prescription drug sales to nursing facilities.

A review of Relator's complaint reveals that Relator has alleged facts which could possibly support the conclusion that Defendants might have submitted successive billings for the same drugs to Medicaid-funded program payors. Relator, however, has not articulated the facts of a specific transaction or a particular set of transactions in which Defendants engaged in the

[11] Relator's attempt to measure the cost of presumptive, successive billings based on extrapolations drawn from more recent refund figures is not persuasive. Refunds are not a valid measure of the cost of successive billings because presumably at least some re-dispensed drugs previously paid for with government funds were dispensed to non-governmental payors.

successive billing for any particular returned and re-dispensed drug. In fact, Relator has failed to identify even one specific instance of double billing. Rather, Relator relies upon inference. Inference alone is insufficient. As the First Circuit held in *Karvelas*, on the issue of transactional detail, "some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)." 360 F.3d at 233. Here, Relator has not provided transactional detail for any claim.

If the Court finds his allegations lacking, Relator requests an opportunity to conduct discovery in an effort to obtain more specific information regarding the claims. On the question of relaxing the particularity requirement to permit "filling in the blanks through discovery," *id.* at 229, the First Circuit has held that such an approach is not appropriate in an FCA qui tam action if the Relator is not already capable of providing at least some transactional detail for at least some specific claims. *Id.* at 229-31. Thus, "a qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery." *Id.* at 231.

In this case, viewing Plaintiff's allegations in the light most favorable to his direct false claim theory, Relator has described a general scheme to submit false claims. "However, such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action." *Id.* at 232. Because Relator has failed to provide any detail involving any particular false claim, his description "does not permit [this Court] to speculate that false claims were in fact submitted." *Id.* at 235.

In short, even if the Court granted Relator leave to amend as requested, Relator's pleading would lack the specificity necessary to proceed on a direct false claim. The amendment, therefore, would be futile.

CONCLUSION

Based on the foregoing analysis, the recommendation is that the Court conclude that Plaintiff's proposed amendment is futile and, therefore, that the Court deny Plaintiff's Motion for Leave to File Amended Complaint to Revise Paragraph 30 (ECF No. 43). The recommendation is also that the Court grant Defendants' Motion to Dismiss the Relator's Amended Complaint (ECF No 37).

NOTICE

> A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within fourteen (14) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within fourteen (14) days after the filing of the objection.
>
> Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 2nd day of July, 2014.